UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

COUNTY OF MONMOUTH, Plaintiff, v. PFIZER INC., Defendant.	Civil Action No. 3:22-CV-02050-MAS-DEA

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT PFIZER INC.'S MOTION TO DISMISS THE COMPLAINT

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INTRODUCTION[1]

This putative class action involves Pfizer's precautionary, voluntary recall of its smoking cessation medication Chantix. Judge Denise Cote in the Southern District of New York already dismissed with prejudice an earlier-filed putative class action based on the same recall and nearly identical allegations, applying New Jersey and New York law. *See Harris v. Pfizer Inc.*, No. 21cv6789 (DLC), 2022 WL 488410 (S.D.N.Y. Feb. 16, 2022). This Court should do the same, as the Complaint fails to state any claim for relief.

Cigarette smoking is the single most preventable cause of death in the United States. It causes more than 480,000 deaths in the U.S. each year—one in five deaths. Cigarette smoking causes an even greater proportion of cancer deaths each year—one in three. For that reason, medical organizations and government agencies universally agree that the most important thing a smoker can do to reduce the risk of cancer and death is to quit smoking. Yet millions of smokers struggle to quit because smoking is highly addictive.

Chantix (varenicline) is a highly effective prescription medicine that helps patients quit smoking. When the U.S. Food and Drug Administration ("FDA") approved Chantix for use in 2006, it proclaimed that Chantix was a "significant

[1] This Motion to Dismiss is filed concurrently with Pfizer's Motion to Transfer to the Southern District of New York. If the Court grants the Motion to Transfer, then it need not consider this Motion to Dismiss.

potential benefit to public health." *See* Matthews Declaration, dated July 5, 2022 ("Matthews Decl."), Ex. 1.[2] Two years later, the United States Public Health Service ("PHS") concluded that Chantix was the ***single most effective*** smoking cessation therapy on the market. By helping patients successfully quit smoking, Chantix has significantly reduced their risk of cancer and other serious health conditions. The medicine also has a strong safety record, supported by an extensive clinical program and more than 15 years of real-world use globally. During that time, no medical, scientific, or regulatory body has suggested that Chantix could cause or increase the risk of cancer.

In 2018, FDA began investigating the potential presence of nitrosamine impurities in medicines. Nitrosamines are organic compounds common in water and foods, including cured and grilled meats, dairy products, and vegetables. Because nitrosamines are ubiquitous in the environment, nearly every human is exposed to some level of nitrosamines in their daily lives. Certain nitrosamines—several of which are present in cigarettes—are classified by the World Health Organization

[2] All exhibits referenced herein refer to the exhibits attached to the Matthews Decl. Citations are included in the Background section. Regarding the exhibits, the Court may consider information from government agencies, including FDA and Centers for Disease Prevention and Control ("CDC"), in evaluating Plaintiff's Complaint as matters of public record. *See, e.g.*, *In re Avandia Mktg. Sales Pracs. & Prod. Liab. Litig.*, 588 F. App'x 171, 174 (3d Cir. 2014) (taking judicial notice of publicly available documents on FDA website).

("WHO") as a probable or possible human carcinogens (i.e., substances that could cause cancer).

In evaluating nitrosamine levels in medicines, FDA and other regulators have established an acceptable daily intake limit ("ADI"), which extrapolates the amount of nitrosamines a person could ingest every single day for her entire life without increasing her theoretical cancer risk associated with the exposure above 1 in 100,000. The ADI assumes that a person will take the medicine ***every day for 70 years***. Because patients are typically prescribed Chantix for twelve to twenty-four weeks only, the 70-year daily intake assumption used to set FDA's ADI limits does not reflect how Chantix is actually prescribed and used: for weeks, not decades.

In July and August 2021, after testing of Chantix identified the presence of a newly-discovered nitrosamine called N-nitroso-varenicline, Pfizer voluntarily recalled consumer lots of the product and offered patients reimbursement for the cost of any unused Chantix. In September 2021, Pfizer further expanded the voluntary recall to include all Chantix lots. FDA press releases at the time informed patients that "there is no immediate risk to patients taking this medication. ***The health benefits of stopping smoking outweigh the theoretical potential cancer risk*** from the nitrosamine." Ex. 2 (emphasis added). Moreover, as FDA acknowledged, "[t]here are ***no data available to directly evaluate the carcinogenic potential of N-nitroso-varenicline***." Ex. 3 (emphasis added). As a result, the Chantix recall was

classified as Class II, which means that FDA determined that "the probability of serious adverse health consequences is ***remote***." Ex. 20 (emphasis added). Thus, the decision to voluntarily recall Chantix was a precautionary measure, not based on evidence of any actual cancer risk associated with real-world use of the medication.

In the wake of this precautionary, voluntary recall, Plaintiff County of Monmouth ("Plaintiff") filed this putative class action, individually and on behalf of all other similarly situated third-party payors ("TPPs"). Plaintiff alleges that the Chantix it and other class members purchased or reimbursed was economically "worthless" and "was so inherently flawed, unfit, or unmerchantable as to have significantly diminished or no intrinsic market value" because it contained a nitrosamine. *E.g.*, Compl. ¶¶ 10, 172, 182.

The Complaint suffers from numerous pleading deficiencies. Faced with similar deficiencies, the Southern District of New York dismissed a putative class action based on the same recall and nearly identical allegations, applying New Jersey and New York law. *See Harris*, 2022 WL 488410. The *Harris* court's holdings apply equally here:

- Plaintiff does not plausibly allege breach of warranty claims because (1) it does not allege any express warranty made by Pfizer, and (2) it cannot plausibly allege that Chantix is unfit for its intended purpose of smoking cessation (Sections II(A) and II(B));
- Plaintiff's fraud-based claims fail because Plaintiff does not plausibly plead a misrepresentation, fraudulent intent or an omission (Section II(C));

- Plaintiff's fraud, negligent misrepresentation, negligence, and negligence per se claims are barred by the economic loss doctrine (Section II(D)); and

- Plaintiff cannot state an unjust enrichment claim where the claim is duplicative of other claims, and it does not allege a benefit that it conferred on Pfizer (Section II(E)).

Plaintiff's claims also fail for additional reasons:

- Plaintiff does not have a cognizable injury and thus lacks Article III standing (Section III);

- Plaintiff's claims other than express warranty are subsumed by the New Jersey Products Liability Act ("NJPLA") (Section IV);

- The Magnuson-Moss Warranty Act ("MMWA") does not apply to consumer items regulated by the FDA (Section V); and

- Plaintiff's violation of state consumer protection laws fails to state any claim for relief (Section VI).

For these reasons, the Court should dismiss the Complaint in its entirety and with prejudice.

BACKGROUND[3]

A. Cigarette Smoking Causes Cancer.

Tobacco use, particularly cigarette smoking, is the single most preventable cause of death in the United States. Ex. 4. Each year, cigarette smoking causes more than 480,000 deaths in the United States—about one in every five deaths. Ex. 4. Many of the health risks of smoking arise because tobacco smoke contains at least

[3] Pfizer assumes the well-pled allegations in the Complaint are true only for purposes of this motion, unless they are contradicted by other allegations, documents referenced in the Complaint, or judicially noticeable facts.

70 chemicals—including tobacco-specific nitrosamines—that cause cancer. Ex. 5. Overall, one in three cancer deaths is caused by smoking (Ex. 6), and, on average, smokers die 10 years earlier than nonsmokers. Ex. 7.

Quitting smoking ***significantly decreases*** an individual's risk of cancer. According to the CDC:

> Quitting smoking lowers the risks for cancers of the lung, mouth, throat, esophagus, and larynx. ... Within 5 years of quitting, your chance of getting cancer of the mouth, throat, esophagus, and bladder is cut in half. Ten years after you quit smoking, your risk of dying from lung cancer drops by half. If nobody smoked, one of every three cancer deaths in the United States would not happen.

(Ex. 8).

B. Quitting Smoking is Difficult.

While nearly 7 in 10 adult cigarette smokers want to stop smoking, less than 8% are successful. Ex. 7. It is a "very difficult" habit to break because nicotine, the active ingredient in cigarette smoke, is highly addictive. Ex. 1 at 1. Approximately 34 million American adults and more than a billion people worldwide are addicted to nicotine. Exs. 7-10. The high relapse rate of smokers seeking to quit also is attributable to a failure to use proven smoking cessation interventions, such as Chantix. Ex. 10 at 24.

C. Chantix is Safe and Effective.

On May 11, 2006, after finding that Chantix had "significant potential benefit to public health," FDA approved the medication as the first new smoking cessation

treatment to enter the U.S. market in more than a decade. Ex. 1 at 1. Chantix is intended for short-term use only. As prescribed and stated on the label, Chantix is designed to be taken for 12 or 24 weeks total. Exs. 11, 12. In 2020, the CDC explained that "[V]arenicline [Chantix] … [is] ***much safer*** than smoking. … If you keep smoking, you will keep getting exposed to the hundreds of harmful chemicals in cigarette smoke. Quit-smoking pills are used for a short time compared to continuing to smoke." Ex. 13 (emphasis added).

Before Chantix, there was a significant unmet need for treatment options to help smokers break their addiction to tobacco. The only forms of FDA-approved smoking cessation therapies were nicotine-replacement therapies ("NRT") and bupropion, a medication originally developed and marketed as an antidepressant. Ex. 10 at 17; *see also* Ex. 14 at 44. Just two years after its introduction, PHS concluded that Chantix was the single most effective smoking cessation therapy on the market. Ex. 14 at 109, 121.

Chantix has a "long track record" of demonstrated efficacy and "safe[ty]." Ex. 13. Chantix has been studied extensively in more than 200,000 smokers in the past fifteen years. Ex. 15.

D. FDA's Investigation of Nitrosamines in Medicines.

Nitrosamines are a class of organic compounds having the chemical structure of a nitroso group bonded to an amine. Ex. 17 at 3. Nitrosamines are ubiquitous in

the environment; they are common in water and foods, including cured and grilled meats, dairy products, and vegetables. Ex. 16. "Everyone is exposed to some level of nitrosamines." *Id*. Certain nitrosamines are classified as probable or possible human carcinogens by the International Agency for Research on Cancer based on laboratory testing, such as rodent carcinogenicity studies. Ex. 17 at App'x B; *see also* Ex. 2.

While nitrosamines are ubiquitous in the environment, FDA did not anticipate that nitrosamines would be present in drug products. Ex. 17 at 1. FDA is still "working to determine the source of these impurities." Ex. 16. By February 2021, it had identified seven potential nitrosamines that theoretically could be present in drug products. Ex. 17 at 4.

In response to the unexpected discovery of the potential presence of nitrosamines in other companies' medicines, in September 2020, FDA published a non-binding Nitrosamine Guidance document ("Nitrosamine Guidance") for industry, which it updated in February 2021. Ex. 17. The Nitrosamine Guidance does not establish legally enforceable responsibilities; instead, it reflects FDA's "current thinking" and "should be viewed only as recommendations." *Id*. at 2. The Nitrosamine Guidance recommends that pharmaceutical manufacturers take steps to detect and prevent unacceptable levels of nitrosamines. *Id*. at 1.

E. FDA's ADIs for Certain Nitrosamines, Including N-Nitroso-Varenicline.

FDA has published ADIs for certain nitrosamines. *Id.* at 10. An ADI represents the daily intake level, which, if consumed every day for a period of ***70 years***, could create a theoretical lifetime cancer risk of 1 in 100,000. *Id.* at App'x B.

A series of assumptions inform the FDA's calculation of the ADI and are common across all nitrosamines. *Id.* FDA uses the most conservative carcinogenicity data available for the specific nitrosamine at issue. *Id.* The calculation of the ADI assumes that the exposed person weighs approximately 110 pounds and will take the medicine daily for 70 years. *Id.* Because of these assumptions, FDA acknowledges that, "[a] drug product intended for only short-term use … poses ***less risk*** than a drug product intended for chronic use." *Id.* at n.30 (emphasis added).

The portion of the ADI calculation that varies across nitrosamines is the amount, in grams, of a specific nitrosamine that results in a 50% tumor incidence rate in the laboratory animals most sensitive to that nitrosamine (e.g., rats): a value called the "TD_{50}." *Id.* at App'x B. Because N-nitroso-varenicline was not a previously known nitrosamine, there was "no data available to directly evaluate [its] carcinogenic potential" that would establish a TD_{50}, and, thus, the ADI is not based on N-nitroso-varenicline data. Ex. 3; *see also* Ex. 17 at App'x B. As a result, as advised in the Nitrosamine Guidance and reported by FDA, "information available

on closely related nitrosamine compounds was used to calculate lifetime exposure limits for N-nitroso-varenicline." Ex. 3. In other words, data based on ***another*** nitrosamine was used to calculate N-nitroso-varenicline's ADI—under the assumption that the comparison nitrosamine will have a similar carcinogenicity profile. Ex. 17 at App'x B.

Based on these assumptions, the FDA-calculated ADI for N-nitroso-varenicline is 37 ng/day. Ex. 18; *see also* Ex. 17, at App'x B. Thus, a 110-pound female who consumed 37 ng of N-nitroso-varenicline ***every day for 70 years*** would have a theoretical (albeit unproven) 1 in 100,000 chance of developing cancer. In contrast, smoking causes one in three cancer deaths. Ex. 6 at 1.

F. The Discovery of N-Nitroso-Varenicline in Chantix.

From July to September 2021, despite FDA concluding that there was "no data available to directly evaluate the carcinogenic potential of N-nitroso-varenicline" (Ex. 3), Pfizer voluntarily recalled Chantix 0.5 mg and 1 mg tablets as a precautionary measure because they may contain levels of N-nitroso-varenicline above FDA's ADI. Ex. 2. Despite the voluntary recall, FDA informed patients that "***there is no immediate risk to patients taking [Chantix]***" since while "N-nitroso-varenicline ***may be*** associated with a potential increased cancer risk in humans," . . . [t]here are ***no data available to directly evaluate the carcinogenic potential of N-nitroso-varenicline***." Ex. 3 (emphasis added). Any theoretical "increased cancer

risk [is] associated with long-term use," and Chantix is intended for short-term use only. *Id.*

As such, FDA advised patients "taking recalled [Chantix] … continue taking their [Chantix] until their pharmacist provides a replacement or their doctor prescribes a different medication that treats the same condition." Ex. 3. And, due to the obviously overwhelming cancer risk from smoking, FDA explained that "***[t]he health benefits of stopping smoking outweigh the cancer risk from the nitrosamine***." *Id.* (emphasis added).

G. Plaintiff's Allegations.

Like the plaintiff in *Harris*, Plaintiff here attempts to assert economic losses as its alleged injury stemming from payment for or reimbursement to individual patients for Chantix prescriptions—these are not personal injury or product efficacy claims. 2022 WL 488410, at *2. The Complaint alleges that Pfizer's actions and omissions made Plaintiff overpay for a "worthless" product. Compl. ¶ 10. Plaintiff further alleges "[n]o reasonable TPP (including Plaintiff)" would have purchased or reimbursed Chantix if it had been aware of the potential presence of a nitrosamine and the alleged risk associated with Chantix. *Id.* ¶ 143. Despite characterizing Chantix as "worthless," Plaintiff does not allege that the medication was ineffective.

ARGUMENT

Plaintiff does not allege personal injury or product efficacy claims and instead attempts to establish an improper "no-injury" product liability class action against Pfizer. "The striking feature of a typical no-injury class is that the plaintiffs have either not yet experienced a malfunction because of the alleged defect or have experienced a malfunction but not been harmed by it." *Coghlan v. Wellcraft Marine Corp.*, 240 F.3d 449, 455 n.4 (5th Cir. 2001). Such plaintiffs "have not suffered any physical harm or out-of-pocket economic loss." *Id*. But an injury is a necessary element of every cause of action, and courts generally forbid recovery without harm. *Whitmore v. Arkansas*, 495 U.S. 149, 155 (1990) (the "alleged harm must be actual or imminent, not conjectural or hypothetical"). Unsurprisingly, then, courts routinely dismiss these types of no-injury cases based on either a failure to state a claim under Rule 12(b)(6) or a lack of Article III standing under Rule 12(b)(1). The *Harris* court did just that—dismissing with prejudice under Rule 12(b)(6) the first-filed putative class action lawsuit concerning Chantix and nitrosamines. *See* 2022 WL 488410, at *3–9.

The same outcome is appropriate here. Plaintiff fails to state plausible claims for breach of warranty, fraud, negligent misrepresentation, negligence, negligence per se, unjust enrichment, and violations of consumer protection laws. Moreover, Plaintiff does not allege a personal injury nor another legally cognizable injury. In

addition, the NJPLA subsumes every claim except for Plaintiff's express warranty claim. Accordingly, all of Plaintiff's claims should be dismissed.

I. LEGAL STANDARD

The Court should grant a motion to dismiss if the pleading fails to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). A Rule 12(b)(6) motion to dismiss should be granted where the pleading fails to contain "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). The pleading must contain more than labels, conclusions, a formulaic recitation of the elements of a cause of action, and naked assertions devoid of further factual enhancement. *Id*. The "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555; *see also Iqbal*, 556 U.S. at 678 (the plausibility standard "asks for more than a sheer possibility that a defendant has acted unlawfully").

The Court should also grant a Rule 12(b)(1) motion to dismiss for lack of subject matter jurisdiction based on the legal insufficiency of a claim. *Kalick v. United States*, 604 F. App'x 108, 111 (3d Cir. 2015). Courts lack jurisdiction when the plaintiff does not have Article III standing. *In re Johnson & Johnson Talcum*

Powder Prod. Mktg., Sales Pracs. & Liab. Litig., 903 F.3d 278, 284 (3d Cir. 2018). The plaintiff bears the burden of establishing standing. *Id.*

II. PLAINTIFF'S EXPRESS WARRANTY, IMPLIED WARRANTY, FRAUD-BASED, NEGLIGENCE AND UNJUST ENRICHMENT CLAIMS FAIL FOR THE SAME REASONS AS IN *HARRIS*.

The Southern District of New York in *Harris*, applying New Jersey law, dismissed with prejudice the express warranty, implied warranty, fraud-based, negligent misrepresentation, negligence, negligence per se and unjust enrichment claims. The Court should reach the same result.

A. Plaintiff Fails to State an Express Warranty Claim.

Just as the court reasoned in *Harris*, Plaintiff's express warranty claim should be dismissed. New Jersey has adopted the Uniform Commercial Code's definition of express warranty. *See* N.J. Stat. Ann. § 12A:2–313; N.Y. U.C.C. § 2–313. To bring a claim for breach of warranty, a plaintiff must plausibly allege that the defendant breached some affirmation, promise, or description related to the goods that became a "basis for the bargain." *Liberty Lincoln-Mercury, Inc. v. Ford Motor Co.*, 171 F.3d 818, 824 (3d Cir. 1999).

The Complaint does not plausibly allege, however, that Pfizer breached any express warranty. Plaintiff alleges only that the "presence of nitrosamines" renders Pfizer's medication "non-bioequivalent (that is, not the same) to listed Chantix, thus

breaching [Pfizer's] express warranties of sameness." Compl. ¶ 138. However, as the *Harris* court held,

> The presence of a nitrosamine does not mean that the medication consumers received was not Chantix, or that it did not contain the active ingredient varenicline. The [Complaint] has not alleged that Pfizer issued any express warranty that their medication was completely safe or free from nitrosamines. Chantix is itself a brand name drug. Its name therefore confers no warranty that it is identical to anything except itself. Accordingly, the presence of nitrosamines does not provide a basis for a breach of express warranty claim.

2022 WL 488410, at *7; *see also In re Avandia Mktg. Sales Pracs. & Prod. Liab. Litig.*, 588 F. App'x 171, 178 (3d Cir. 2014) ("Because . . . D'Apuzzo does not allege GSK made unqualified guarantees of safety or effectiveness, D'Apuzzo has failed as a matter of New Jersey law to state an express warranty claim.")

Plaintiff therefore has not plausibly alleged that Pfizer breached any express warranty.

B. Plaintiff Fails to State a Breach of Implied Warranty Claim.

Plaintiff's implied warranty claim fails because Plaintiff does not allege that Chantix is unfit for its intended purpose: smoking cessation. To state an implied warranty claim, Plaintiff must allege "(1) that a merchant sold goods, (2) which were not 'merchantable' at the time of sale, (3) injury and damages to the plaintiff or its property, (4) which were [ ] caused proximately and in fact by the defective nature of the goods, and (5) notice to the seller of injury." *Hoffman v. Nordic Nats., Inc.*, No. 12-CV-05870, 2014 WL 1515602, at *7 (D.N.J. Apr. 17, 2014) (quoting *Marcus v.*

BMW of N. Am., LLC, 687 F.3d 583, 600 n.8 (3d Cir. 2012)). The implied warranty of merchantability does not require that the goods be perfect or that they fulfill a buyer's every expectation; it only requires that the goods sold be of a minimal level of quality. *See N.J. Transit Corp. v. Harsco Corp.*, 497 F.3d 323, 330 (3d Cir. 2007) (under New Jersey law, an implied warranty of merchantability "simply means that the thing sold is reasonably fit for the general purpose for which it is manufactured and sold").

Plaintiff alleges that the presence of nitrosamines in Chantix renders it "non-merchantable and not fit for its ordinary purposes." Compl. ¶141. This claim fails because the Complaint does not plausibly allege that the warranty was breached. As the *Harris* court held, the Complaint "does not allege that Chantix failed to fulfill its purpose of helping its users to quit smoking." 2022 WL 488410, at *8. Instead, Plaintiff argues "that the warranty was breached because Chantix could not be safely used." *Id.*; *see also* Compl. ¶¶ 143, 171, 177–182. But the Complaint "does not allege that the contamination harmed [consumers], or even put them at significant risk." *Harris*, 2022 WL 488410, at *8. In fact, in announcing the recall, the FDA stated that there was "no immediate risk" to patients taking Chantix, and it urged patients to continue taking the medication even after the recall. Exs. 2, 3, 19.

Plaintiff has therefore failed to plausibly allege that Chantix was unfit to help consumers quit smoking.

C. Plaintiff's Fraud-Based Claims Fail for Several Reasons.

As the *Harris* court reasoned, Plaintiff's fraud-based claims fail because Plaintiff has not alleged a misstatement by Pfizer, fraudulent intent or a claim for fraudulent omission.

1. Plaintiff Alleges No Misstatement by Pfizer.

In New Jersey, the five elements of common-law fraud are: (1) a material misrepresentation of a presently existing or past fact; (2) knowledge or belief by the defendant of its falsity; (3) an intention that the other person rely on it; (4) reasonable reliance thereon by the other person; and (5) resulting damages. *Gennari v. Weichert Co. Realtors*, 148 N.J. 582, 610 (1997). A cause of action for fraud may be based on an omission rather than affirmative statement, but "only if the non-disclosing party has a duty to disclose." *Remington Rand Corp. v. Amsterdam-Rotterdam Bank, N.V.*, 68 F.3d 1478, 1483 (2d Cir. 1995); *see also Rosenblit v. Zimmerman*, 166 N.J. 391, 406 (2001) (fraudulent concealment claim requires "a legal obligation to disclose.") (citation omitted).

A party alleging fraud must "state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). To meet Rule 9(b)'s heightened pleading standard, the complaint must "'plead (1) a specific false representation of material fact; (2) knowledge by the person who made it of its falsity; (3) ignorance of its falsity by the person to whom it was made; (4) the intention that it should be acted

upon; and (5) that the plaintiff acted upon it to his [or her] damage.'" *Garfield v. Shutterfly, Inc.*, 857 F. App'x 71, 79-80 (3d Cir. 2021) (internal quotation omitted). "This requires plaintiffs to specify 'the who, what, when, where, and how: the first paragraph of any newspaper story.'" *Id*. (quoting *Calif. Pub. Employees' Ret. Sys. v. Chubb Corp*., 394 F.3d 126, 144 (3d Cir. 2004)). Courts routinely dismiss fraud claims where plaintiffs have not stated with particularity how the statements are purportedly false. *See, e.g., In Riddell Concussion Reduction Litig.*, 77 F. Supp. 3d 422, 438 (D.N.J. 2015) (dismissing claim; "Plaintiffs' failure to identify with specificity the marketing statements which they allege are false, which proved fatal under Rule 9(b), compels the same result under Rule12(b)(6)"); *Henderson v. Volvo Cars of N Am., LLC*, No. 09–4146 (DMC)(JAD), 2010 WL 2925913, at *3 (D.N.J. July 21, 2010) (dismissing claim because plaintiffs "only made vague assertions with respect to their affirmative misrepresentation fraud claims").

The *Harris* court dismissed nearly identical allegations to those alleged in Plaintiff's Complaint. 2022 WL 488410, at *4. Like here, the plaintiff alleged that "Pfizer made two misrepresentations: first, that the product consumers purchased was 'Chantix', as approved by the FDA; and second, that the product contained only the active ingredient varenicline." *Id*.; *see* Compl. ¶¶ 30, 132, 137, 191, 207, 208, 209. According to Plaintiff, "these representations were false or misleading because the medication was contaminated by N-nitroso-varenicline." *Compare Harris*, 2022

WL 488410, at *4 *with* Compl. ¶¶ 137, 191, 195, 196, 207, 208, 209. But as the *Harris* court correctly observed, "neither the product label nor the medication guide state that varenicline is the only biologically active ingredient in Chantix." 2022 WL 488410, at *4 (emphasis in original). "And presence of a contaminant does not render the brand name on the label false – contaminated Chantix is still Chantix." *Id*. The Complaint alleges "no facts to suggest that the Chantix [Plaintiff] purchased [or reimbursed] differs in any way from the drug approved by the FDA, much less that it differs so much as to no longer be Chantix." *Id*.

Accordingly, the Complaint does not sufficiently allege that Pfizer made a misstatement under Rule 12(b)(6), let alone the heightened pleading standard of Rule 9(b).

2. Plaintiff Has Not Alleged Fraudulent Intent.

Plaintiff cannot plausibly allege Pfizer's fraudulent intent when it is undisputed that N-nitroso-varenicline is a newly-discovered nitrosamine. Again, the *Harris* court dismissed nearly identical allegations to those alleged in Plaintiff's Complaint. Just as here, the plaintiff alleged that "Defendant knowingly failed to disclose and concealed the contamination of the defective Chantix with the intent that Plaintiff and members of the New Jersey Subclass rely on said concealment." *Compare Harris* Compl. ¶ 62 *with* Compl. ¶ 200.

As in *Harris*, the Complaint "fails to allege that Pfizer had knowledge that [Chantix] was contaminated by N-nitroso-varenicline at the time [Plaintiff] purchased [or reimbursed] it." 2022 WL 488410, at *4. The Complaint alleges that one of Pfizer's distributors[4] was warned in October of 2020 that its supply of varenicline was at risk of contamination with nitrosamines. Compl. ¶¶ 102–105. "These allegations, however, at most only show that Pfizer may have known that its medication was at risk of contamination by late 2020. They do not show that Pfizer knew or believed that Chantix was actually contaminated, particularly when [consumers] purchased Chantix." *Harris*, 2022 WL 488410, at *4. Even more so here, where the vast majority of transactions Plaintiff is seeking damages for are pre-October 2020 reimbursements. Compl. ¶ 20. Thus, this Court, like the *Harris* court, should find that these allegations are "insufficient to give rise to a 'strong inference' that Pfizer had 'knowledge of their misstatements' falsity and an intent to induce reliance.'" 2022 WL 488410, at *4 (internal quotation omitted); *see also Banco Popular N.A. v. Gandi*, 184 N.J. 161, 174 (2005).

[4] Subsequent briefing on a motion to transfer an analogous consumer class action pending in the Southern District of Florida has included a factual showing that Apotex is not, and has never been, a Pfizer distributor. Ex. 21; *see Burke v. MacArthur*, No. CV 15-6093(RMB), 2015 WL 5970725, at *6 (D.N.J. Oct. 13, 2015) ("In considering dismissal for failure to state a claim . . . matters of public record, orders, items appearing in the record of the case and exhibits attached to the complaint may also be taken into account.").

3. Plaintiff Has Not Plausibly Pled a Claim for Fraudulent Omission.

As the *Harris* court noted, "[a]t its core, the issue giving rise to the plaintiffs' claims is … that Pfizer failed to disclose any nitrosamine contamination." 2022 WL 488410, at *4. A plaintiff may bring a fraud claim based on an omission rather than an affirmative misrepresentation only if the non-disclosing party has "a legal obligation to disclose." *Rosenbilt v. Zimmerman*, 166 N.J. 391, 406, 766 A.2d 749 (2001). No duty to disclose exists "unless such disclosure is necessary to make a previous statement true or the parties share a special relationship." *Lightning Lube, Inc. v. Witco Corp.*, 4 F.3d 1153, 1185 (3d Cir. 1993) (internal quotations and citation omitted). "Three categories of relationships give rise to a duty to disclose: (1) fiduciary relationships, such as principal and agent, client and attorney, or beneficiary and trustee; (2) relationships where one party expressly reposits trust in another party, or else from the circumstances, such trust necessarily is implied; and (3) relationships involving transactions so intrinsically fiduciary that a degree of trust and confidence is required to protect the parties." *Id*. (citation omitted).

Here, just like in *Harris*, Plaintiff has "not plausibly alleged a duty to disclose." 2022 WL 488410, at *5. Nowhere does the Complaint allege (nor could it) that Plaintiff is in a special or fiduciary relationship with Pfizer. *Id*. Nor does the Complaint plausibly allege that Pfizer had knowledge that Chantix was contaminated, or that Pfizer made a prior or partial statement "that was rendered

false or misleading by any omission." *Id*. Plaintiff suggests that "Chantix's product and active ingredient labels are misleading because they do not disclose the presence of a nitrosamine contaminant. But that omission does not render either the brand name 'Chantix' or the active ingredient label 'varenicline' false or misleading—those terms correctly identify the product that . . . [Plaintiff] actually purchased [or reimbursed]." *Id.*

Accordingly, the Complaint has not plausibly alleged a fraudulent omission claim.

D. Plaintiff's Fraud, Negligent Misrepresentation, Negligence, and Negligence Per Se Claims are Barred by the Economic Loss Doctrine.

The economic loss doctrine precludes Plaintiff's tort claims. Here, Plaintiff alleges fraud, negligent misrepresentation, negligence, and negligence per se claims.

The economic loss rule "preclude[s] plaintiffs from recovering under fraud and other intentional tort theories of liability where the tort claims are based on the same facts as the breach of contract claims." *Bracco Diagnostics, Inc. v. Bergen Brunswig Drug Co.*, 226 F. Supp. 2d 557, 562 (D.N.J. 2002) (dismissing fraud claim); *see also Alloway v. Gen. Marine Indus., L.P.*, 149 N.J. 620, 641 (1997) (dismissing negligence claim). Such claims should be brought under the law of contract, which is designed to provide a remedy for disappointed economic expectations. *See Alloway*, 149 N.J. at 641.

Both Plaintiff's tort and contract claims assert that the medication Plaintiff purchased or reimbursed failed in its intended purpose of being Chantix. *Compare* Compl. ¶¶ 163–189 *with* Compl. ¶¶ 190–216, 227–243. This Court repeatedly has dismissed tort claims that "comprise[ ] the exact same allegations that form Plaintiff's breach of contract claim." *Plastic Surgery Ctr., P.A. v. Cigna Health & Life Ins. Co.*, No. 17–2055 (FLW) (DEA), 2018 WL 2441768, at *7 (D.N.J. May 31, 2018); *see also Smith v. Citimortgage, Inc.*, No. 15-7629 (JLL), 2015 WL 12734793, at *7 (D.N.J. Dec. 22, 2015) (dismissing negligent misrepresentation claim under economic loss doctrine); *Neuss v. Rubi Rose, LLC*, No. CV162339MASLHG, 2017 WL 2367056, at *9 (D.N.J. May 31, 2017) (J., Shipp) (same); *Marte v. Deutsche Bank Nat'l Tr. Co.*, No. CV 2:15-0869 (CCC), 2016 WL 6403082, at *4 (D.N.J. Oct. 26, 2016) (dismissing negligence per se claim). The *Harris* court dismissed the plaintiff's negligent misrepresentation claim on the same basis. 2022 WL 488410, at *6 (finding that "the alleged misrepresentation here – that the drug the plaintiffs purchased was Chantix with the active ingredient varenicline – is not a separate statement that induced the plaintiffs to enter into a contract with Pfizer; it is the statement that the plaintiffs allege actually constituted the contract that Pfizer breached").

In addition, Plaintiff asserts it is a public entity that "manages operations of sixty county departments" and "operates a self-funded health insurance plan … and

directly pays for all or a portion of its insureds' … prescription costs." Compl. ¶18. Plaintiff is not a patient who actually ingests the medication; Plaintiff is a sophisticated entity that paid negotiated prices for medications taken by its insureds. The economic loss doctrine, thus, should be applied with full force. *See, e.g.*, *Travelers Indem. Co. v. Dammann & Co.*, 594 F.3d 238, 248 (3d Cir. 2010) ("In keeping with the purpose of the economic loss doctrine, New Jersey courts have consistently held that contract law is better suited to resolve disputes between parties where a plaintiff alleges direct and consequential losses that were within the contemplation of sophisticated business entities. . .").

The economic loss doctrine therefore bars Plaintiff from asserting its tort claims.

E. The Unjust Enrichment Claim Fails.

To state an unjust enrichment claim, Plaintiff must allege that (1) Pfizer received a benefit from Plaintiff, and (2) that the retention of the benefit by Pfizer is inequitable. *D.R. Horton Inc. — N.J. v. Dynastar Dev., L.L.C.*, No. MER-L-1808-00, 2005 WL 1939778, at *18 (N.J. Super. Ct. L. Div., Mercer Cnty. Aug. 10, 2005) (dismissing unjust enrichment claim). Unjust enrichment does not provide an independent cause of action under tort law. *See Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris, Inc.*, 171 F.3d 912, 936 (3d Cir. 1999). Instead, it functions primarily as a justification for restitution remedies when a defendant has

been "enriched . . . beyond its contractual rights." *VRG Corp v. GKN Realty Corp.*, 135 N.J. 539, 554 (1994).

As the *Harris* court found, the only allegations in the Complaint "specific to the unjust enrichment claim state that Pfizer accepted and kept the plaintiffs' money obtained from selling Chantix." 2022 WL 488410, at *9; *see also* Compl. ¶ 225. "But the plaintiffs do not explain why their unjust enrichment claim is distinct from their other claims, or distinct from a conventional tort or contract action." *Harris*, 2022 WL 488410, at *9. For this reason, the court dismissed the unjust enrichment claim. *Id*.

Plaintiff's unjust enrichment claim also fails because it did not confer a benefit directly upon Pfizer. "New Jersey law requires a direct relationship between the parties." *Maniscalco v. Brother Int'l Corp.*, 627 F. Supp. 2d 494, 505-506 (D.N.J. 2009) (dismissing unjust enrichment claim). A "benefit conferred upon a retailer not sharing in profits with the product manufacturer ***does not result*** in the manufacturer's unjust enrichment." *Alin v. Am. Honda Motor Co*., No. CIV A 08-4825 KSH, 2010 WL 1372308, at *15 (D.N.J. Mar. 31, 2010) (dismissing claim) (emphasis added). Here, Plaintiff does not allege a direct relationship between itself and Pfizer, which is fatal to its claim. *See, e.g.*, *Hale v. Stryker Orthopaedics*, CIV 08-3367(WJM), 2009 WL 321579, at *4 (D.N.J. Feb. 9, 2009) (dismissing claim). Accordingly, the unjust enrichment claim should be dismissed.

III. PLAINTIFF HAS NOT PLED AN INJURY AND THUS LACKS STANDING.

A. Plaintiff Cannot State a Claim Without an Injury.

Plaintiff's claims also suffer from a fundamental defect—Plaintiff was not injured. To state a claim for fraud and breaches of warranty, Plaintiff must plead an injury. *See Hoffman v. Nordic Nats., Inc.*, No. 12-CV-05870 (SDW)(MCA), 2014 WL 1515602, at *5, 7 (D.N.J. Apr. 17, 2014) (dismissing fraud and warranty claims for failure to plead injury). A plaintiff receives the benefit of her bargain when she "has entirely consumed a product that has functioned for her as expected." *In re Johnson & Johnson Talcum Powder*, 903 F.3d at 280-281; *see also Rivera v. Wyeth-Ayerst Labs*, 283 F.3d 315, 320 (5th Cir. 2002) (a plaintiff suffers no economic injury where it "paid for an effective [product], and … received just that—the benefit of [its] bargain").

Here, Plaintiff alleges that it purchased or reimbursed Chantix—an FDA-approved medication—and nothing more. Plaintiff concedes its beneficiaries ingested the medication, Compl. ¶¶ 83, 94, and it never alleges that Chantix was ineffective. *See generally id.* The fact that hundreds of beneficiaries used Chantix suggests that it effectively aided smoking cessation efforts. *See id*. ¶ 22. Indeed, FDA urges consumers to continue taking Chantix until a replacement therapy can be prescribed because "***there is no immediate risk to patients taking [Chantix]***" and "[t]here are ***no data available to directly evaluate the carcinogenic potential of N-***

nitroso-varenicline." Exs. 2, 3 (emphasis added). Thus, Plaintiff has not been injured.

B. Plaintiff Lacks Article III Standing.

Because Plaintiff has not been injured, the Court should dismiss the Complaint under Rule 12(b)(1) for lack of Article III standing. At an "irreducible constitutional minimum," Plaintiff must show it has ***personally suffered*** some actual or threatened injury due to Pfizer's conduct and that the injury is "fairly traceable" to the "challenged action" and is "likely … [to be] redressed by a favorable decision." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992). "[A] plaintiff does not have Article III standing when she pleads economic injury from the purchase of a product, but fails to allege that the purchase provided her with an economic benefit worth less than the economic benefit for which she bargained." *In re Johnson & Johnson Talcum Powder*, 903 F.3d at 290.

In *In re Johnson & Johnson Talcum Powder*, the plaintiff alleged that she suffered an economic injury when she purchased baby powder that was "improperly marketed" because the manufacturer did not inform consumers of the risk of developing ovarian cancer. *Id.* at 282. The plaintiff did not allege that the baby powder caused her physical injury, that she had ovarian cancer, or had an increased risk of developing cancer. *Id.* at 281. The Third Circuit affirmed the district court's holding that the plaintiff lacked standing because "precedent requires the plaintiff to

do more than simply pair a conclusory assertion of money lost with a request that a defendant pay up." *Id.* at 288 n.12 (citing cases). Similarly, here, Plaintiff has not alleged physical injuries and has only alleged conclusory assertions of money lost for its purchase or reimbursement of Chantix.

Likewise, in *James v. Johnson & Johnson Consumer Companies, Inc.*, purchasers of baby shampoo brought a consumer class action alleging that the manufacturer included a toxic ingredient in the shampoo. No. 10–cv–03049 (DMC)(JAD), 2011 WL 198026, at *2 (D.N.J. Jan. 20, 2011). The plaintiffs did not allege that their children suffered any physical harm from the shampoo; rather, they argued that they had standing because they would not have purchased the shampoo had they known of its alleged toxicity. *Id.* The Court disagreed, holding that "[o]nce the product had been consumed . . . there was no economic injury for Plaintiffs to complain of, and the fear of future injury is legally insufficient to confer standing. Plaintiffs received the benefit of their bargain so long as there were no adverse health consequences, and the product worked as intended." *Id.*; *see also In re Schering Plough*, 678 F.3d 235, 248 (3rd Cir. 2012) (standing did not exist where "pure conjecture" was required to conclude that the defendants' conduct ultimately caused injury); *Rivera*, 283 F.3d at 319 (no standing for patients who purchased medication but suffered no physical or emotional injury and alleged only economic injury).

This is not a situation like *In re Valsartan, Losartan, & Irbesartan Products Liability Litigation*, where the Court determined that the plaintiffs' injury-in-fact allegations were sufficient to establish standing because the plaintiffs alleged that (1) their purchase of a generic version of a brand medication allegedly contaminated by a nitrosamine rendered the generic medication "worth less than their non-contaminated equivalents," or (2) they suffered "economic loss from having to purchase replacement medication due to the voluntary recalls." MDL No. 2875 (RBK/JS), 2021 WL 100204, at *8–10 (D.N.J. Jan. 12, 2021).

Neither applies here. First, Plaintiff allegedly purchased or reimbursed brand Chantix, not its generic equivalent. As Plaintiff concedes, "Chantix has not faced generic drug competition since its launch." Compl. ¶ 59. Thus, Plaintiff's allegation that the brand Chantix it purchased or reimbursed was worth less than non-contaminated equivalents is factually implausible since no such equivalent existed. *See, e.g.*, *id*. ¶¶ 8, 143, 178; *see also Harris*, 2022 WL 488410, at *8 ("Chantix is itself a brand name drug"). Second, because there was no alternative to brand Chantix at the time, Plaintiff cannot plausibly allege that it suffered economic loss from having to purchase replacement medication.[5]

[5] Plaintiff allegedly seeks "the purchase price of any replacement medications" and "the cost to replace" Chantix, Compl. ¶ 172 and Prayer for Relief, but those allegations lack any factual support in the Complaint since Plaintiff does not allege that it actually purchased replacement medication.

The *Harris* court did not dismiss the complaint before it on standing grounds because there was no binding Second Circuit precedent holding that a plaintiff asserting such a claim lacks Article III standing. 2022 WL 488410, at *2–3. The Third Circuit, however, has such precedent—and numerous district courts have also so held. *See In re Johnson & Johnson Talcum Powder*, 903 F.3d at 284; *see also Thorne v. Pep Boys Manny Moe & Jack Inc.*, 980 F.3d 879, 886 (3d Cir. 2020); *James*, 2011 WL 198026, at *2; *Estrada v. Johnson & Johnson*, No. 16-7492, 2017 WL 2999026, at *4 (D.N.J. July 14, 2017), *aff'd* 903 F.3d 278 (3d Cir. 2018); *Hubert v. General Nutrition Corp*., No. 15-cv-01391, 2017, WL 3971912, at *8 (W.D. Pa. Sep. 8, 2017); *Kimca v. Sprout Foods, Inc.*, No. CV 21-12977 (SRC), 2022 WL 1213488, at *8–9 (D.N.J. Apr. 25, 2022).

Accordingly, Plaintiff received the benefit of its bargain and has no valid claim of injury. Plaintiff therefore lacks Article III standing.

C. Plaintiff Lacks Standing to Seek Injunctive Relief.

Plaintiff's request for injunctive relief also fails because it has not alleged a risk of future harm. To have standing to obtain injunctive relief, Plaintiff must show that it is "likely to suffer future injury" from Pfizer's ongoing conduct. *In re Johnson & Johnson Talcum Powder*, 903 F.3d at 292 (citation omitted).

Plaintiff cannot demonstrate standing for injunctive relief because it is already "well aware" of the purported increased "risk" of cancer and thus cannot be misled

in the future. *Id.* at 293 ("Estrada has sued Johnson & Johnson for failing to warn her of certain health risks. To state the obvious, then, she is presently aware of those risks . . . She is simply not at risk of suffering an economic 'injury,' and we will not give cognizance to this sort of 'stop me before I buy again' claim."); *see also Kimca*, 2022 WL 1213488, at *10 ("Because Plaintiffs have brought this lawsuit, it is common sense that they are now aware of the alleged risks associated with the Baby Food Products and, thus, will not be deceived by Sprout's marketing in the future."); *McNair v. Synapse Group, Inc*., 672 F.3d 213 (3d Cir. 2012) (finding that former customers did not have standing to pursue injunctive relief because they already were aware of the defendant's allegedly deceptive practices).

Moreover, Pfizer voluntarily recalled all lots of Chantix, so there is nothing to enjoin. *See, e.g.*, *Darius Int'l, Inc. v. Young*, No. CIV. A. 05-6184, 2008 WL 1820945, at *49 (E.D. Pa. Apr. 23, 2008) (claim for injunctive relief is moot when party voluntarily stops selling a product). Thus, Plaintiff's request for injunctive relief must be dismissed.

IV. THE NJPLA SUBSUMES ALL BUT ONE OF PLAINTIFF'S CLAIMS.

Even if Plaintiff had pled a cognizable injury conferring standing, the NJPLA subsumes every claim except for its express warranty claim. The NJPLA is "the sole method to prosecute a product liability action." *Tirrell v. Navistar Int'l, Inc.,* 248 N.J. Super. 390, 398-99 (App. Div. 1991), cert. denied, 126 N.J. 390 (1991). The NJPLA

was enacted "to limit the expansion of products-liability law" and "to limit the liability of manufacturers so as to balance[] the interests of the public and the individual with a view towards economic reality." *Zaza v. Marquess & Nell, Inc.*, 144 N.J. 34, 47 (1996) (quotations and citations omitted). A product liability action is "any claim or action brought by a claimant for harm caused by a product, ***irrespective of the theory underlying the claim,*** except actions for harm caused by breach of an express warranty." N.J. Stat. Ann. § 2A:58C-1(b)(3) (emphasis added). Thus, under New Jersey law, a plaintiff only has a compensable loss for a harm caused by a product if she can allege "personal injury" or "physical damage to property other than the product itself." N.J.S.A. 2A:58C-1(b)(2).

Here, Plaintiff has pled neither personal injury nor physical damage. Instead, Plaintiff seeks to "shoehorn" its "failure to warn" allegations into other causes of action when "it is clear from the innumerable boilerplate allegations that [its] claims sound in products liability causes of action." *Barrett v. Tri-Coast Pharm., Inc.*, 518 F. Supp. 3d 810, 824 (D.N.J. 2021). This attempt fails. As the New Jersey Supreme Court has explained:

> Were there any doubt about the essential nature of the claims asserted by plaintiffs, a careful reading would demonstrate that they sound in products liability causes of action. The central focus of plaintiffs' complaints is that defendants were aware of dangers associated with lead—and by extension, with the dangers of including it in paint intended to be used in homes and businesses—and failed to warn of those dangers. ***This classic articulation of tort law duties, that is, to warn of or to make safe, is squarely within the theories included in the PLA.***

In re Lead Paint Litig., 924 A.2d 484, 503–04 (N.J. 2007) (tort claim subsumed by the NJPLA) (emphasis added); *see also Indian Brand Farms v. Novartis Crop Prot., Inc.*, 890 F. Supp. 2d 534, 548 (D.N.J. 2012) (finding plaintiff's NJCFA and fraudulent misrepresentation claims were subsumed by the NJPLA because they were based on facts that supported a failure to warn claim).

For example, in *O'Donnell v. Kraft Foods, Inc.*, the plaintiffs brought a consumer class action asserting a violation of the New Jersey's Consumer Fraud Act ("NJCFA") and alleging that the defendant's hot dogs would increase plaintiffs' risk of cancer and that they were not warned of the carcinogenic dangers. No. CIVA 09-4448, 2010 WL 1050139, at *3 (D.N.J. Mar. 18, 2010). The Court dismissed the complaint as subsumed by the NJPLA and held that:

> Plaintiffs are seeking damages ... due to the increased risk of cancer they allege arises from consumption of a product. Plaintiffs' attempt to tack a [consumer fraud] remedy onto the underlying products liability claim does not alter the analysis: their theory that they are entitled to recovery of their purchase price for the hot dogs depends upon Defendants' ***alleged failure to warn of their increased risk of cancer,*** a failure of 'adequate warnings or instructions' covered by the PLA.

Id. at *3 (emphasis added).

Similarly, in *Barrett v. Tri-Coast Pharm., Inc.*, the plaintiff brought fraud and warranty claims due to an infection allegedly due to his medication's purported bacterial contamination. 518 F. Supp. 3d at 824. The Court rejected the plaintiff's attempt to "shoehorn his [product liability] allegations into other causes of action"

when the case was "premised on the product being defective" and thus was a "failure to warn" case. *Id.* The Court also noted that the fraud-based claims were subsumed by the NJPLA "because the alleged misrepresentation would not be actionable if ... [the] pharmaceuticals were not contaminated." *Id.*; *see also Darby v. Merck & Co.*, 949 A.2d 223, 276–77 (N.J. Super. Ct. App. Div. 2008) (consumer fraud claims subsumed by NJPLA because "the gravamen of [the] claim [i]s that [a pharmaceutical company] marketed [a medicine] fully aware of its ... risk[s] [and] made misrepresentations[ ] and ... omis[sions]" in connection with its marketing); *Mendez v. Shah*, 28 F. Supp. 3d 282, 302 (D.N.J. 2014) (fraud and misrepresentation claims subsumed by NJPLA because "[a]lthough [the] plaintiff stresses the representations made by" the defendant, including "safe and effective use," the "essence of her claim is that the misrepresentations resulted in physical harm from the product"); *In re Valsartan, Losartan, & Irbesartan Prod. Liab. Litig.*, No. MDL 2875 (RBK/KW), 2021 WL 364663 (D.N.J. Feb. 3, 2021) (NJPLA subsumed claims including negligence, negligence per se, breach of implied warranty, fraud, negligent misrepresentation, and violation of state consumer protection statutes).

The same result follows here. The Complaint centers around Plaintiff's allegation that Pfizer failed to warn that Chantix contains unsafe levels of N-nitroso-varenicline. *See* Compl. ¶¶ 60, 92, 101, 122, 138, 147. Thus, the NJPLA provides the sole basis for potential relief here and Plaintiff's fraud, negligent

misrepresentation, negligence, negligence per se, NJCFA, implied warranty, MMWA, and unjust enrichment claims should be dismissed.

V. PLAINTIFF FAILS TO ALLEGE A BREACH OF THE MMWA.

Plaintiff's MMWA claim fails for additional independent reasons. To plead a violation, a plaintiff "must assert there is a valid warranty, the product was presented for repair during the warranty period, and the manufacturer failed to conform the product to the provisions of the warranty within a reasonable amount of time or number of repair attempts." *In re Valsartan, Losartan, & Irbesartan Prod. Liab. Litig.*, No. MDL 2875 (RBK-JS), 2021 WL 222776, at *20 (D.N.J. Jan. 22, 2021).

This Court has held repeatedly that "the MMWA prohibits warranty claims involving FDA-regulated items." *In re Valsartan*, 2021 WL 222776, at *21; *Hernandez v. Johnson & Johnson Consumer, Inc.*, No. 3:19-cv-15679-BRM-TJB, 2020 WL 2537633, at *5 (D.N.J. May 19, 2020) (citing cases). Chantix is an FDA-approved prescription medicine. Compl. ¶ 3. As such, "the MMWA is inapplicable to any alleged express or implied warranty claims on [its] labeling." *Hernandez*, 2020 WL 2537633, at *5. Even if the MMWA were applicable, the claim further fails because Plaintiff has not properly alleged the requisite underlying state law warranty claim. *See supra* Sections II(A) and II(B). Thus, the claim should be dismissed.

VI. PLAINTIFF HAS NOT PLAUSIBLY PLED VIOLATIONS OF STATE CONSUMER PROTECTION LAWS.

The Complaint asserts violations of more than 50 state, District of Columbia, and Puerto Rico consumer protection laws. Compl. ¶¶ 217–221. The allegations are conclusory, so it is unclear what theory of liability the Complaint alleges. Plaintiff undertakes no effort to identify the "fraudulent and deceptive acts, omissions, or concealment" upon which these claims are based, *id*. ¶ 221, other than to refer generically to each and every allegation in the Complaint that came before them. *Id*. ¶ 217.

"Several courts have held that merely listing statutes that could provide possible causes of action without explaining even the broadest contours of how those statutes were violated 'is insufficient to state a claim.'" *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig*., No. 16-5073, 2017 WL 4642285, at *13 (E.D. Pa. Oct. 17, 2017) (quoting *In re Aluminum Warehousing Antitrust Litig.*, MDL No. 13-2481, 2014 WL 4743425, at *1 (S.D.N.Y. Sept. 15, 2014) (quoting *In re Trilegiant Corp*., 11 F. Supp. 3d 82, 124 (D. Conn. Mar. 28, 2014)) (further quotations omitted)); *see also McGarvey v. Penske Auto Grp., Inc.*, 639 F. Supp. 2d 450, 465 (D.N.J. 2009), reconsideration granted on other grounds (dismissing state consumer protection law claims because "[p]laintiffs do not even set forth the elements of the fifteen causes of action they assert . . . or explain how the fifteen listed statutes apply to the facts of this case").

Count VI of the Complaint alleges exactly the "unadorned, the-defendant-unlawfully-harmed-me accusation" disallowed under *Twombly* and *Iqbal*. *Iqbal*, 556 U.S. at 678. There are no well-pleaded facts, and "[t]hreadbare recitals of the elements of a cause of action . . . do not suffice." *Id*. Accordingly, this claim must be dismissed as conclusory.

Even if Plaintiff had properly pled the claims for all 50 states, the District of Columbia, and Puerto Rico (and it has not), Plaintiff also lacks standing to assert claims under the consumer protection statutes beyond New Jersey. "Plaintiff … lacks standing to assert claims under the laws of the states in which he does not reside, or in which he suffered no injury." *McGuire v. BMW of N. Am., LLC*, 2014 WL 2566132, at *6 (D.N.J. June 6, 2014). Therefore, Plaintiff "lack[s] standing to assert claims on behalf of unnamed plaintiffs in jurisdictions where Plaintiffs have suffered no alleged injury." *Ponzio v. Mercedes-Benz USA, LLC*, 447 F. Supp. 3d 194, 223 (D.N.J. 2020) (dismissing claims for states where the plaintiffs did not reside).

Here, Plaintiff resides in New Jersey and claims only to have purchased for or reimbursed New Jersey employees. Compl. ¶¶ 18–19. Thus, consumer protection claims under laws other than New Jersey's must be dismissed.

CONCLUSION

Pfizer respectfully requests that the Court dismiss Plaintiff's Complaint in its entirety and with prejudice.

Dated: July 5, 2022

Respectfully submitted,

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